

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|--|----------------------|---------------------|------------------|
| 10/640,980 | 08/14/2003 | Lawrence B. Jansen | 112455-145576 | 9232 |
| | 25943 7590 09/13/2007 SCHWABE, WILLIAMSON & WYATT, P.C. | | | |
| PACWEST CE | NTER, SUITE 1900 | NASSER, ROBERT L | | |
| 1211 SW FIFTH AVENUE PORTLAND, OR 97204 | | | ART UNIT | PAPER NUMBER |
| , | | | 3735 | |
| | | | | <u></u> . |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 09/13/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Best Available Copy | Ц | † | | | | |
|---|--|--|---------------|--|--|--|--|
| | | Application No. | Applicant(s) | | | | |
| | | 10/640,980 | JANSEN ET AL. | | | | |
| | Office Action Summary . | Examiner | Art Unit | | | | |
| | : | Robert L. Nasser | 3735 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | |
| Status | | | | | | | |
| 1)⊠ R | esponsive to communication(s) filed on 31 AL | <u>igust 2007</u> . | | | | | |
| 2a) 🔲 T | This action is FINAL . 2b)⊠ This action is non-final. | | | | | | |
| 3)∏ S | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Dispositio | ; n of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-4,6-9,20-28 and 31</u> is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6)⊠ C | 6) Claim(s) 1-4, 6-9, 20-28, 31 is/are rejected. | | | | | | |
| 7) 🔲 C | laim(s) is/are objected to. | | | | | | |
| 8)□ :0 | laim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | | |
| 9)∐ TI | ne specification is objected to by the Examine | ſ. | | | | | |
| 10)∐ TI | 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority un | der 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
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| Attachment(s) | | | | | | | |
| | of References Cited (PTO-892) | 4) Interview Summary | | | | | |
| | of Draftsperson's Patent Drawing Review (PTO-948) ition Disclosure Statement(s) (PTO/SB/08) | Paper No(s)/Mail Da 5) Notice of Informal F | | | | | |
| | io(s)/Mail Date | 6) Other: | | | | | |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/31/2007 has been entered.

Before applying art, the examiner notes that applicant has stated that the term "surround' dopes not require that the membrane cover the active surface on all sides. To the best of the examiner's understanding, then, applicant merely intends the term to mean contained with and covered by, for example encircled by, and this is the interpretation that will be applied to the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-9, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough et al 4703756. Gough et al shows a device including a electrochemically active surface, a membrane system 14 and 22 containing an enzyme (see column 4, line 36), a membrane 20 adhering to the electrochemically active surface and at least one nub 32 of a dielectric naterial (glass) extending outwardly from the active surface and supporting the membrane, where the membrane "substantially" covers the nub and the surface. The examiner notes that the membrane 14 encircles and covers a portion of the electrodes and nub. Alternatively, the system certainly encircles and covers the nub and electrodes. With respect to claim 2, the nub is an annular plate

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in as much as the nub of Gough appears to have the same structure as the nub of applicant's disclosure. With respect to claim 3, the active surface is part of a lengthwise body. With respect to claim 4, the body has a circular cross section. With respect to claim 5, the active surface is located circumferentially around a lengthwise body 24 of circular cross section. Claim 6 is rejected in that the nubs are annular plates. Claim 7 is rejected in that the nub is longitudinally displaced from the active surface in as much as applicant's nubs are longitudinally spaced. Claim 8 is rejected in that there are multiple membranes 14 and 22. Claim 9 is rejected in that the membrane system includes an enzyme layer. 22, and the nub extends transversely from the active surface. With respect to claim 31, there are multiple nubs forming a cavity which is surrounded by the membrane system.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-9, 21-25, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough 4671288 in view of Gough 4703756. Gough '288 shows a device including an electrochemically active surface, 18 extending centrally of 3 nubs 27 or dielectric material, and a membrane system 24 containing an enzyme 20 that adheres to the nub and surface. In addition, Gough '288 has an exterior housing 10 covering the device. Gough '756 further teaches that it is advantageous to make the outer housing 14 be a semi permeable membrane permeable to oxygen, and relatively impermeable to glucose, to enhance the electrochemical reaction in a glucose sensor (see column 4, lines 4-17). Hence, it would have been obvious to modify Gough

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288 to make the housing be a semi permeable membrane, to provide improved results. Hence, Gough would include a membrane system that includes an enzyme made up of elements 10, 20, and 24. The examiner notes that the claims do not require that the entire membrane system include the enzyme only that there be an enzyme in the system. Claims 2 and 6 are rejected in that at least the central nub of Gough '288 is an annular plate. Claims 3 and 4 are rejected in that the system of Gough '288 is a circular cross-sectional, lengthwise body. Claim 7 is rejected in that the nub is longitudinally displaced from the active surface in as much as applicant's nubs are longitudinally spaced. Claim 8 is rejected in that there are multiple membranes 10 and 24. Claim 9 is rejected in that there is an enzyme layer 22. Claim 20 is rejected in that there are 3 nubs. Claim 21 is rejected in that the active surface 18 extends through the nubs. Claims 22 and 23 are rejected in that the exact shape of the membrane system is not stated to be for a particular purpose or to solve a stated problem. As such, it is the examiner's position that the shape of the membrane system would have been a matter of design choice for one skilled in the art. Claim 24 is rejected in that the membrane is on an external surface. Claim 25 is rejected in that the examiner takes official notice that platinum is a material that is well known to be used for the purposes of element 18 of Gough. Hence, it would have been obvious to modify Gough to use platinum, as it is merely the substitution of one known equivalent material for another. With respect to claim 31, there are multiple nubs on the Gough device which is surrounded and covered by the membrane system.

Claims 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gough '288 in view of Gough '756, as applied to claims 1-4, 6-9, and 21-25 above, further in view of Saitoh et al 6144871. Saitoh further teaches that glass or glass epoxy and polyimide are known to be

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equivalent insulators in the art. Hence, it would have been obvious to modify the above combination to use polyimide for the elements 27, as it is merely the substitution of one known equivalent material for another.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough 288 in view of Gough '756, as applied to claims 1-4, 6-9, and 21-25 above, further in view of Wilson 5165407. As noted by applicant in the specification, Wilson teaches that a permselective layer and an interferent excluding layer are well known to be used in a glucose sensor. Hence, it would have been obvious to modify Gough to use a layer like that of that of Wilson, as it is merely the substitution of on known sensor configuration for another.

Applicant's arguments filed 8/31/2007 have been fully considered but they are not persuasive.

In the response filed 9/19/2006, applicant has argued that the membrane system of Gough '756 does not surround both the active surface and nub. It is the examiner's position that the enzyme containing membrane 22 surrounds the electrode and a portion of the nub. Alternatively, the membrane system containing elements 14 and 22 certainly surrounds the nub and electrodes, as a system may surround something even if every element of the system does not surround it.

With respect to the Gough '288 reference, applicant has argued that the enzyme containing gel does not cover the nub and active surface. This may or may not be true, but claim only requires that t system cover both elements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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RLN September 4, 2007 Ret & nexy